ANNEX H

QUALITY ASSURANCE PROJECT PLAN

U.S. Army
Chemical Materials Agency

Project Manager for
Non-Stockpile Chemical Materiel

Explosive Destruction System
at Dugway Proving Ground
Quality Assurance Project Plan

Final
Revision 2

U.S. Army
Chemical Materials Agency

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Final
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March 2009

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1. INTRODUCTION

Quality assurance and quality control (QA/QC) procedures are used during data collection and analysis to determine whether prescribed procedures are being followed and systems are operating within required limits. An effective QA/QC program provides assurance that deviations from established procedures and safe working conditions are identified in a timely manner. The objective of an effective QA/QC program is that workers and the public are protected from potential hazards. The QA/QC program also provides assurance that conclusions derived by analytical analyses are representative determinations.

2. CRITICAL MEASUREMENTS

Appendix H-1 contains tables listing the "critical" measurements for the Explosive Destruction System (EDS) at Dugway Proving Ground (DPG). **Table H-1-1** lists the critical measurements and identifies the measuring devices, collection frequency, and frequency and type of additional quality control (QC) measurements associated with each measurement. For planning purposes, **Table H-1-2** contains a summary of analytical samples anticipated for this project. The actual number of samples may vary depending on circumstances. QA/QC procedures for air monitoring samples are provided in the Site-Specific Monitoring Plan (**Annex E** to the EDS at DPG Destruction Plan).

3. RESPONSIBILITIES OF KEY QUALITY ASSURANCE (QA) PERSONNEL

Key QA personnel are identified in **Table H-1**. Each QA representative has an independent reporting chain within the organization that is independent of the EDS System Manager. Each organization is responsible for ensuring the QA representative is qualified to perform assigned duties.

Table H-1. Key QA Staff

Title or Function/Name	Immediate Supervisor/Senior Manager
PMNSCM Onsite Representative	CMA-RMD
EDS System Manager	PMNSCM
EDS Site Safety Officer/QA Manager	ECBC
PMNSCM Project Manager	PMNSCM
Monitoring QA Manager	ECBC Monitoring Chief

Notes:

CMA	=	U.S. Army Chemical Materials Agency
ECBC	=	Edgewood Chemical Biological Center
EDS	=	Explosive Destruction System
PMNSCM	=	Project Manager for Non-Stockpile Chemical Materiel
QA	=	quality assurance
RMD	=	Risk Management Directorate

3.1 QA Representative Responsibilities

The QA representative's responsibilities include:

- Coordinating and conducting audits under the direction of the Project Manager for Non-Stockpile Chemical Materiel (PMNSCM)
- Ensuring that methodologies documented in the QA/QC plan are followed
- Ensuring personnel understand the QA aspects of their duties
- Documenting and communicating deviations from this plan to management, the EDS QA Coordinator, DPG, and PMNSCM
- Ensuring compliance with the QA objectives of paragraph 4.

3.2 Common Responsibilities

The following QA responsibilities are shared by all EDS participants:

a. *Training.* Each organization will conduct training for employees for the purpose of meeting requirements of local regulations and policies and this QA/QC plan. Personnel will be fully qualified to perform their duties. Each organization will maintain training records for assigned employees for 3 years after project completion.

b. *Control of Nonconformance and Corrective Actions.* Organizations will provide oversight of the work quality of employees. Audits and surveillance of job performance may be conducted on a noninterference basis. Workers will report nonconformances with established policies and procedures to area supervisors and QA representative.

c. *Document Control.* Each organization provides document control for the documents generated. Document control will be in accordance with procedures specified in this Plan and by each organization's internal policies. The EDS System Manager will receive a copy of each document for the onsite files. At the conclusion of operations, the EDS onsite files will be released to DPG.

4. QA/QC OBJECTIVES

4.1 Certification and Validation Requirements

To provide data that meet project requirements, it is necessary to ensure that the level of data uncertainty is acceptable. To accomplish this, Edgewood Chemical Biological Center (ECBC) shall perform a certification and validation process for operators, instruments, and methods to confirm that analytical processes are suitable for use. Certification and validation will be performed in accordance with the latest version of the ECBC QC plan.

4.2 Additional QA Objectives

Procedures and documents containing technical or QA requirements will be prepared, approved, and distributed in a controlled manner to ensure that current information and direction are available in the workplace. Changes to procedures and documents also will be controlled. Obsolete procedures and documents will be removed from the workplace when the new ones become available. The EDS System Manager is responsible for keeping site documentation up to date.

Identification, collection, indexing, maintenance, and final disposition of records are controlled by procedures in the *Modern Army Recordkeeping System* [Army Regulation (AR) 25-400-2]. This ensures preservation of documents and other media that prescribe technical or QA requirements, or provide evidence of QA achievement. Documentation retained as records of environmental compliance or compliance with PMNSCM policies will be stored in a manner that minimizes the risk of damage or destruction. This may include maintaining dual storage at separate locations or single storage in facilities that meet National Fire Protection Association 232 requirements (current edition and addenda). During EDS operations, this is the responsibility of the EDS System Manager. The PMNSCM Onsite Representative and EDS QA Manager must approve exceptions to this requirement.

Operations and maintenance procedures will be used where the absence of these procedures could have an adverse effect on quality or safety. Such procedures will provide detailed work sequences, and sequence, type, and extent of QC inspections, tests, and acceptance criteria. Operations and maintenance will be performed under controlled conditions that ensure a suitable working environment, compliance with all requirements, and availability of required equipment. DPG will retain documentation of QA inspections, compliance with requirements, and availability of equipment. The PMNSCM Onsite Representative and EDS QA Manager must approve exceptions to this requirement.

Changes to design and procedures will be evaluated to determine the impact to safety and environment. These evaluations will be documented. A configuration management program administered by PMNSCM will control changes.

5. AIR MONITORING

Air monitoring is conducted to ensure that the EDS operations are performed safely and in accordance with this Plan. The primary objective of air monitoring is to detect conditions that may cause workers to be exposed to chemical agent vapors. Air monitoring strategies and equipment are described in the Site-Specific Monitoring Plan (**Annex E** to the EDS at DPG Destruction Plan).

6. SAMPLE HANDLING PROCEDURES

Numerous samples are generated during the course of EDS operations. These samples include Depot Area Air Monitoring System (DAAMS) tube samples and solid and liquid waste samples for agent screening. All of these samples must be transported from the point of collection to a laboratory for analysis. To ensure that analytical results can be properly attributed to the sample taken, various procedures are followed as described in the following paragraphs.

6.1 Chain of Custody (COC)

Sample COC adheres to COC documentation requirements described by the U.S. Environmental Protection Agency (USEPA) National Enforcement Investigation Center.

Evidence of sample custody is traceable from the time the sample is collected until the sample is disposed of after analysis. At the time of collection, the appropriate part of the COC form is filled out. The original and one copy are placed in a plastic bag inside the secured sample transport container.

Each sample bottle or tube is labeled and each sample container sealed using individual COC seals. Tracking the sample container to and from the field is accomplished by reference to the identification number on the seal. In addition, each sample container has a COC form. COC information also is recorded in the field logbook.

6.2 Shipping Containers and Custody Seals

For samples analyzed at the onsite laboratory, an appropriate sample carrier will be used that prevents the sample containers from breaking or becoming dissociated from their labels. When appropriate, ice packs will be used to maintain a temperature no greater than 4°C from the field to the laboratory.

6.3 Sample Identification and Traceability

ECBC operates a system of assigning unique sample identification (ID) numbers to each sample taken before its release to the laboratory. The information from the field tag is transferred to the tag program, which assigns the unique sample ID number and generates a sample tag, scratch log, and data sheet. The sample tag is placed with the field tag and the sample is delivered to the laboratory. The sample ID numbers and corresponding data shall go into 40-year storage.

DAAMS tubes used in the collection of samples by ECBC personnel have a unique ID number. A field tag will be attached to each DAAMS tube carrier. The field tag shall contain both DAAMS tube numbers, initial and final flow rates, pump number and location. Start and stop of sample collection times will be added as necessary.

The DAAMS ID number is generated by a personal computer (PC)-based program. The program generates a unique number for each sample using the last two numbers of the year, the number of the month in which the sample is collected, the day the sample is collected, and the location of the tag computer where the data were input (for example, 0209180125-M01). This indicates that the particular sample was taken 18 September 2002, was sample number 125 for the month, and the data were input on the tag computer at location M01. The status and custody of a sample shall be tracked using the sample tag.

The sample tag remains with the sample until the analysis is determined to be in control. The tag then is removed from the sample, attached to the corresponding chromatogram, filed in the laboratory records for 1 year, and then transferred to the U.S. Army Chemical Materials Agency (CMA) Historical Research and Response Team's storage area.

For all other samples (liquid, residue, solids, etc.), the sample ID number must be unique to each sample. To ensure traceability and uniqueness of the sample identification, the sample ID number should incorporate the sample type, date, and time that the sample was collected. Any deviations from standard procedures shall be noted in the comments section of the sample COC form. An example might be: DS0421971010003. This would indicate the sample was a decontaminant solution (DS) sample, collected on April 21, 1997 (042197) at 1010 hours (1010), as the third sample collected (003). Additional identifiers could include S (soil sample), T (colorimetric sorbent tube), R (residue), and LR (liquid rinse).

The sample identification system shall be documented along with a method that relates the field data to the samples. All documentation of the samples shall be performed with indelible ink. If corrections are made to the data, the error will be crossed out once and initialed by the person documenting the data.

6.4 Sampling Frequency

Waste samples are collected as required in the Waste Management Plan (**Annex F**) and Sampling Plan (**Annex G**).

6.5 Disposition of Unused Sample Material

Samples that have been collected but not used or leftover sample material will be decontaminated and managed with other liquid wastes or will be emptied back into the waste container from which it originated.

7. FIELD MEASUREMENTS

Field measurements are data collected by equipment operators with real-time or near real-time (NRT) instruments that do not require samples managed in a laboratory. The following paragraphs describe the instruments used to make field measurements.

7.1 Thermocouples

Thermocouples are calibrated by comparing the temperature reading on the digital readout unit to the temperature of a National Institute of Standards and Technology (NIST)-traceable thermometer. If discrepancy occurs, the digital readout unit is adjusted to indicate temperature readings that agree with the NIST traceable thermometer. The calibration is performed in accordance with the specifications of the thermocouple manufacturer.

7.2 Pressure Sensors and Gauges

Pressure sensors and gauges are calibrated to a NIST-traceable standard in accordance with the manufacturer's specifications.

7.3 Time Measuring Devices

Except for setting the clocks to local time, time measuring devices do not require calibration beyond the original calibration performed by the manufacturer. Manufacturer certification of QC is generally supplied with each instrument.

7.4 Wind Direction and Speed Measuring Devices

The anemometer and wind vane are operated in accordance with the requirements of the USEPA *Quality Assurance Handbook for Air Pollution Measurement Systems: Volume IV* (EPA-600/4-90-003) and the corresponding manufacturer's specifications.

7.5 Scales

If precision balances are used, they will be calibrated using NIST-traceable weights and in accordance with the manufacturer's specifications.

7.6 Flowmeters

Flowmeters are calibrated in accordance with procedures specified in the USEPA *Quality Assurance Handbook for Air Pollution Measurement Systems: Volume II Ambient Air Specific Methods* and the corresponding manufacturer's specifications.

7.7 DAAMS Tube Sample Analysis

DAAMS tube samples are analyzed in an onsite laboratory. The analysis is performed using a gas chromatograph (GC) with flame photometric detector (FPD) or a mass spectrometer (MS). See the ECBC Internal Operating Procedure (IOP) MT-13 for details. Copies of all IOPs will be onsite.

7.8 Equipment Maintenance Frequency

Table H-2 presents the recommended calibration and maintenance intervals for EDS components and support equipment. **Table H-3** lists the recommended maintenance procedures for laboratory equipment.

8. DATA REDUCTION, VALIDATION, AND REPORTING

The following describe procedures for collection, organization of accurate information, clear and concise reporting of data.

8.1 Operations Data

Standardized forms and logbooks are used to record operations and sampling data. The EDS System Manager and the QA Manager review collected data in their entirety in the field. Errors or discrepancies will be noted in the operations field books. The EDS System Manager has the authority to institute corrective actions. At a minimum, the QA Coordinator is notified of all deviations from standard protocol. A portion of the data and calculations is manually rechecked against the logbooks and original data sheets. Operations data are maintained in the EDS files.

Table H-2. Recommended EDS Components and Support Equipment for Calibration[a]

Description	Calibration Interval	Source
Containment Vessel Subsystem		
Manifold Pressure Gauge	Annually/As Required	SPX
Hydraulic Nut Subsystem		
Pressure Gauge, Hydraulic Nut Pump	Annually/As Required	SPX
Rotary Agitation Subsystem		
Movi-Drive	As Required	SEW
Reagent Supply Subsystem		
Helium Regulator, 0 to 400 psig (Air Panel)		Matheson
Pressure Relief Valve		
Waste Transfer Subsystem		
Waste Drum Scales (Mechanical)	Annually/As Required	FLOQUIP
Electrical Subsystem		
Watlow 96 Controllers (Vessel and Reagent Manifold)	As Required	Watlow
Watlow 97 Controller	Annually/As Required	Watlow
Thermocouples	As Required	Minco
DMMS (480 meters)	As Required	Electro Industries
Explosive Opening Subsystem		
Fire Set	Annually/As Required	SNL
Helium Supply and Leak Detection Subsystem		
Helium Pressure Regulator	Annually/As Required	Matheson
Vacuum Gauge	Annually/As Required	Ashcroft
DOT Helium Cylinder	Annually/As Required	Matheson
Calibrated Leaks (142 Helium Leak Detector)	2 years	ALCATEL
Leak Detector	As Required	ALCATEL
Pressure Relief Valve	As Required	

Table H-2. Recommended EDS Components and Support Equipment for Calibration[a] (Continued)

Description	Calibration Interval	Source
Ancillary Equipment and Tools		
Torque Wrench, 3/8-inch Drive	Annually/As Required	Snap-On Tools
Torque Wrench, 1/2-inch Drive	Annually/As Required	Snap-On Tools
Multimeter, Fluke	Annually/As Required	Fluke/Buckles-Smith
Calibrator, Fluke	Annually/As Required	Fluke/Buckles-Smith
Calipers, Digital	Annually/As Required	Buckles-Smith

Notes:

[a] Table identifies the recommended list of equipment, tools and parts for the EDS and support equipment for calibration. The recommended calibration intervals listed are from the vendor or manufacturers documentation, unless otherwise indicated in the calibration interval column.

DOT = Department of Transportation
psig = pounds per square inch gauge

Table H-3. Recommended Maintenance Procedures for Laboratory Equipment

Equipment	Procedure/Frequency	Spare Parts
Analytical Balance	Daily: Calibrate with standard weights, clean up spills. Annually: Service by TMDE/Manufacturer	
Gas Chromatograph/ Mass Spectrometer	Daily: Check gas supply, check column flow, check detector temperature. As Needed: Check level of oil in mechanical pumps and diffusion pump, replace electron multiplier, clean source, repair/replace jet separator, replace filaments, perform column maintenance. Semi-Annually: Check oil in mechanical rough pump and change, if necessary. Annually: Vendor supported preventive maintenance	Columns, ferrules, chemical traps
Gas Chromatograph/Flame Photometric Detector	Daily: Check gas supply, check column flow, check detector temperature. As Needed: Perform column maintenance. Annually: Vendor supported preventive maintenance	Columns, ferrules, chemical traps
DAAMS System	Daily: Check flow rates, critical orifices, fittings, and ferrules. As Needed: Perform vacuum pump and sequencer maintenance.	Ferrules, extra pumps
MINICAMS®	Daily: Check gas supply, check temperatures and operating parameters. As Needed: Replace PCT, reactor tubes, analytical columns, clean sample lines, check pump oil level. Semi-Annually: Vendor supported preventive maintenance	PCT, reactor tubes

Notes:

DAAMS = Depot Area Air Monitoring System
PCT = preconcentrator tube
TMDE = Test Measurement and Diagnostic Equipment

8.2 Laboratory Data

Raw data are reduced and quantitative results reported as specified in each analytical method. The laboratory specifies the methods used for data reduction. A portion of the reduced results are checked manually against the bench sheets and raw data. All laboratory reports are maintained in the EDS files.

8.3 Data Validation

Data validation involves the review of data and the acceptance or rejection of that data based on specific criteria. The criteria depend on the type and purpose of the data. The initial step in data validation is a thorough examination of all calculations involved in the reduction of sampling and analytical data. The data validation review is performed independent of the laboratory analyst(s) performing the analytical determinations. A chemist or QA officer will review 100 percent of raw analytical data and an independent reviewer will verify at least 20 percent of the data. The following paragraphs describe additional procedures for treatment of raw data to ensure clear and concise reporting of data.

8.4 Sampling and Operation

At least one series of calculations will be validated by someone other than the person who originally performed the calculations. All data are checked for completeness and are placed in the project data file. The data file also includes all documents associated with the calibration of the sampling and measuring equipment. Any redundant or backup data are used to assist in validating the operational data. The following criteria are used to evaluate field data:

- Use of sampling procedures described in this Plan
- Use of equipment that was calibrated and operated according to Standing Operating Procedure (SOP), manufacturers' guidance, or other guidance approved by the EDS System Manager
- COC of samples and standard traceability.

This validation process includes all samples and collected information such as, but not limited to, leak tests, sample volume calculations, temperature and pressure readings, etc. The data are reviewed for correctness, transcription errors, and compliance with method performance and acceptance criteria.

8.5 Laboratory

Analytical data will be validated by laboratory QC and supervisory personnel by the criteria provided in this Plan. The following criteria will be evaluated to determine the validity of analytical data:

- Used approved analytical procedures
- Used equipment that was calibrated and operated according to approved procedures
- Achieved precision and accuracy comparable to that achieved in previous analytical programs.

8.6 System Performance Data Reporting

Pre-operational and operational reports will be prepared. Copies of the reports will be provided to PMNSCM and DPG.

8.7 Pre-operational Survey

The pre-operational survey provides a basis for PMNSCM to authorize the start of chemical agent operations. This report documents the review of all pertinent documentation, inspection of all process and support equipment and facilities, and witnessing of selected system tests and operations. The pre-operational survey is prepared under the direction of the EDS System Manager and submitted to PMNSCM. A copy will be provided to DPG.

8.8 System Operations Reports

At the close of operations a final operations report will be prepared that summarizes project accomplishments. Each report will include information about the time frame covered by the report, the items that were processed, information on any releases of chemical agent outside of engineering controls, and any equipment or process failures and corrective actions taken. Operations reports will consist of the following sections:

- Executive Summary
- Introduction
- Project Description
- Data Collection Parameters

- System Performance Summary
- Conclusions
- Recommendations.

9. INTERNAL QC CHECKS

The following paragraphs address the internal field and laboratory QC checks implemented to ensure that the QA objectives specified in this plan are met. These are all instruments for which the QA objectives are based on the manufacturers' stated performance specifications. The number and frequency of field QC samples to be collected during operations are described in **Tables H-1-1** and **H-1-2** of **Appendix H-1** to this Quality Assurance Project Plan (QAPjP). All monitoring equipment will be calibrated and challenged in accordance with the latest version of the ECBC quality control plan.

9.1 Reference Material Standards Program

Reference standards are required to calibrate and challenge instruments and to spike QC samples. These solutions must be of known concentration and purity to ensure the validation of analytical results. Requirements for handling standards are located in Department of the Army Pamphlet (DA Pam) 385-61 and Program Manager for Chemical Demilitarization (PMCD) Policy Statement No. 49.

Chemical Agent Standard Analytical Reference Materials (CASARMs) for analytical analysis of chemical agents are developed and distributed by ECBC. CASARMs are chemical agent reference materials that are of characterized composition and purity.

All calibration solutions and standards used in the EDS operations are prepared and maintained under a laboratory standards tracking system. The system ensures that preparation, checking, documentation, storage, and disposal of standards are performed in accordance with the specified procedures and schedules appropriate for each analyte. Various aspects of standards tracking are described in the following paragraphs. The standard solutions used for MINICAMS® calibration and challenges are made using pesticide grade solvent.

9.2 Preparation of Standard Solution

Standard solutions, known as research development, test, and evaluation (RDT&E) dilute standards, will be prepared by ECBC and shipped to the EDS operation site at DPG. RDT&E dilute standards can be handled with the same procedures as the pure solvents. Material Safety Data Sheets are readily accessible for the solvents and chemical agents in the laboratory and EDS Operations Trailer.

Solutions in vials will have the septum replaced before the vial is returned to cold storage. The old septum caps are disposed of as hazardous waste.

9.3 Storage and Handling of Working Standard Solutions

Each working standard solution is stored at a nominal 4°C in a refrigerator within the laboratory. All storage refrigerators and freezers shall have a certified thermometer that is checked once per day. The working standard solutions are allowed to warm to room temperature before being used for calibration or challenges. The working standard solutions are promptly returned to cold storage when immediate use is no longer necessary. Working standard solutions are exposed to as little light as possible.

9.4 Disposal of Working Standard Solutions

Residual calibration and QC working standard solutions are disposed of at the close of operations (after monitoring is completed) in accordance with all applicable Resource Conservation and Recovery Act (RCRA), Department of Transportation (DOT), state, and local regulations. Any standard that has expired or is of questionable purity is disposed of when such condition is noted. The laboratory manager documents disposal of all solutions to allow for traceability and final disposition.

9.5 Chemical Measurement Calibration Requirements

Calibration standards are used to calibrate the MINICAMS and the GC. This type of calibration establishes a relationship between instrument response and the concentration of analyte in the samples. A calibration curve or a calibration point typically represents this relationship. Subsequent sample analysis results are then compared with the calibration curve or point to quantify the amount of analyte present in the sample.

MINICAMS calibration requirements are detailed in ECBC IOP MT-16.

Gas chromatograph/mass spectrometer (GC/MS) and gas chromatograph/flame photometric detector (GC/FPD) calibration requirements are detailed in ECBC IOPs MT-13 and MT-19, respectively.

9.6 Equipment Calibration Labels

Each piece of analytical and monitoring equipment is labeled with a visible indication of its calibration status. As a minimum, the label indicates the date of last calibration, the date due for recalibration, and the initials of the operator.

9.7 Calibration Documentation

Calibration documentation will include a detailed description of the associated calculations, equations, or software programs used. The equation used to calculate the amount of analyte in a sample from a calibration curve is validated and documented in writing before operations. The validation records for the equations are maintained in the monitoring files.

Any proposed changes to the approved calibration procedures, including the chemical solutions, SOPs, software, calculations, or equations, must first be validated and then submitted to PMNSCM, DPG, and the Utah Division of Solid and Hazardous Waste.

The EDS operators will establish and maintain a calibration file for the field monitoring and laboratory analytical equipment. As a minimum, the file will include the following:

- The procedure for calibrating each kind of monitoring and analytical equipment
- Frequency of calibration and the rationale for the periodicity
- Range of the calibration curve
- Calibration acceptance criteria
- Calculations, equations, and evaluation criteria used for analysis of calibration data
- Documentation of each calibration event

- Calibration source, including traceability of calibration equipment and chemicals

- A calibration list of all the monitoring and analytical equipment used to support EDS operations.

The calibration list of all the monitoring and analytical equipment will include the instrument serial number; most recent date of calibration; reference to the location and identification of the detailed calibration procedure, person, or agency that performed the calibration; calibration results; and the next date for recalibration. For equipment that requires frequent calibration, for example MINICAMS, the specific dates of calibration and the results are not required on the calibration list (but they must be on the equipment label).

10. PERFORMANCE AND TECHNICAL SYSTEM AUDITS

The EDS QA program includes both performance and technical system audits as independent checks of data quality. PMNSCM and the EDS QC Coordinator are responsible for ensuring that appropriate audits are conducted. It must be recognized that EDS treatment is a batch process and not continuing operations; therefore, all elements of the audits may not be able to be performed.

10.1 Performance Audits

Performance audits of sampling, analysis, and data handling are in addition to QC checks performed by the operator or analyst. Performance audits are unannounced and will consist of at least one blind sample delivered to the onsite laboratory from ECBC by arrangement with PMNSCM. The results will be compared to predetermined acceptance limits. Performance audits will also consist of at least one over the shoulder observation of the person recording and reading or interpreting the data. Calculations performed by computer will be reviewed using a set of “dummy” raw data for which the calculation results are known.

The following items describe performance audit planning and reporting:

- There will be one performance audit during EDS operations.
- A report of the performance audit results will be distributed to DPG, ECBC, and PMNSCM.
- Investigation and corrective action will be required when unsatisfactory performance is identified.

10.2 Technical System Audits

A technical system audit is a qualitative review to ensure that the quality measures outlined in the QA plan are in place. Technical system audit planning will consist of the elements discussed in the following paragraphs.

10.2.1 Scope. The technical system audit will be implemented under the direction of the EDS QA Coordinator to evaluate, as applicable:

- Organization and management
- Quality system audit and review (review of the yearly CASARM audit report documentation and yearly internal audit report including procedures for maintaining audit files)
- Personnel

- Accommodation and environment
- Equipment and reference materials
- Measurement traceability and calibration
- Test methods
- Handling of chemical warfare materiel (CWM) items
- Records
- Certificates and reports
- Subcontracting of laboratory
- Outside support and supplies
- Issues (findings of previous audits).

10.2.2 Scheduling. A technical audit will take place during the pre-operations period. The start of chemical operations is contingent on the results of this inspection. Only one technical audit is planned; however, PMNSCM may require other technical audits during EDS operations if circumstances indicate such is necessary.

10.2.3 Audit Plans. An audit plan will be prepared, reviewed, and approved by PMNSCM and the EDS QA Coordinator. The audit plan will include:

- Organization and work areas to be audited
- Date and time of the audit
- Basis of audit criteria
- Names and duties of audit personnel
- Checklist that will guide the audit process.

If an audit is not planned for certain areas, the plan will include a statement of justification for not performing an audit of that subject.

10.2.4 Audit Personnel. Personnel who perform audits will not have responsibility for performing the work being audited but will have sufficient knowledge and be allowed sufficient authority and freedom to identify deficiencies and recommend effective corrective action.

10.2.5 Audit Execution. A pre-audit conference will be held between the auditor(s) and representatives of DPG, EDS operators, and PMNSCM site representative to introduce personnel, arrange for access to personnel, documents, and facilities, and to explain how the audit results will be reported.

Daily briefings will be held to inform the PMNSCM site representative and DPG of the progress of the audit, concerns, findings, and to exchange views and gather information.

A post-audit conference will be held between the auditor(s), the PMNSCM site representative, and DPG to inform them of preliminary results.

10.2.6 Audit Reporting. Results will be documented. The audit report will be distributed to EDS operations files, DPG, and PMNSCM.

11. CORRECTIVE ACTION

Each nonconformance identified during performance and technical system audits will be addressed in accordance with the following paragraphs. All EDS personnel have the responsibility to detect problems and implement corrective actions to minimize the effects of these problems on the work quality. The following paragraphs describe correction actions not specifically addressed elsewhere. These include corrective actions required as a result of noncompliance identified by a system operator or identified during a performance or technical system audit.

11.1 Identification, Segregation, and Return

The EDS System Manager will establish and implement procedures to ensure the following:

- Materials, data, and items that do not conform to prescribed technical or quality requirements are marked, tagged, labeled, or otherwise identified as nonconforming.

- Nonconforming materials and items, whose use or further processing has been placed on hold pending resolution of the nonconformance, are segregated from the conforming material and items to the extent necessary to preclude their inadvertent use.

- Activities that do not conform to prescribed technical or quality requirements are documented in field or laboratory notebooks.

- Once materials and items have been identified and appropriate documentation prepared, the EDS System Manager must determine if the materials or items should be returned to the manufacturer, reworked, or destroyed, and then take appropriate action.

11.2 Documentation and Status

Documentation includes identification of the following:

- Nonconforming activity, material, data, or item

- Noncompliance of the activity, material, data, or item with technical or quality requirements

- Individual reporting the nonconformance

- Current status of the activity, material, data, or item (on hold or conditions status)

- Individuals or organizations responsible for resolution

- Type and extent of corrective action that is required to resolve the nonconformance.

In addition, there will be indication of the importance of the nonconformance, information regarding the continuance or stoppage of work associated with each nonconforming activity, material, data, or item.

The status of each nonconformance and the progress of its resolution is documented and routinely reviewed to ensure prompt attention to conclusion.

11.3 Required Actions

Required actions are identified in the following paragraphs.

11.3.1 Remedial Actions. Remedial actions are those actions taken to correct the immediate noncompliance.

11.3.2 Investigative Actions. Investigative actions are those actions taken to identify the extent of the problem. For example, if an instrument is found to be out of calibration, the operator will conduct an investigation into the impact of this condition on all work performed since the last calibration.

11.3.3 Root Cause. Root cause refers to identification of the most basic cause that can be reasonably identified and that management has control over to fix.

Responsibility for implementing the corrective action is assigned to a specific person and that person's acceptance of the assignment is noted. The implementation and effectiveness of the corrective action is verified by personnel other than those responsible for carrying out the corrective action.

11.4 Reporting

Corrective action documentation will be distributed to PMNSCM, and a copy will be kept in the EDS QA files.

12. QA REPORTS

QA representatives provide information in sufficient detail and timeliness to assess the overall effectiveness of the QA program. The ECBC monitoring chief will provide copies of all monitoring and QC data (after verification and peer review) to PMNSCM, and DPG. There are four major types of QA reports as described in the following paragraphs.

12.1 Monthly Reports on QA Activities

This summary report describes significant problems observed and corrective actions taken, changes to the QA organization, and notice of the distribution of revised documents controlled by the QA organization.

12.2 Monthly Reports on Measurement Quality Indicators

This report includes the assessment of QC data gathering over the period, the frequency of analyses repeated due to unacceptable QC performance, and when appropriate, the reason for the unacceptable performance and description of corrective action taken.

12.3 Reports on QA Assessments

This report includes the results of internal or external technical system audits and performance audits and plan for correcting identified deficiencies. This is an event driven report with one report prepared for each audit performed.

12.4 Incident Reports

Incident reports will be prepared covering specific QA incidents. Incidents involving the release or suspected release of chemical agent outside of engineering controls require a written report within 48 hours of discovery. Each report will be assigned an incident report number and a category of occurrence (emergency, unusual, off-normal). The report will include sufficient detail to document the nature of the incident (including location, personnel, and equipment involved), when and by whom the incident was discovered, date and time notifications were made, immediate actions taken and results, results from monitoring or sampling and analysis performed, description of personal injuries and equipment damage (including personnel, equipment, and area decontamination requirements), description of the direct, contributing, and root causes of the incident, and the EDS Manager's evaluation of the incident including impact of the incident on the project and whether further evaluation is required.

13. CALCULATION OF DATA QUALITY INDICATORS

The following describe how the data generated by the internal QC checks are used to calculate the quantitative data quality indicators of precision, accuracy, and method of detection limit.

13.1 Precision

Precision is an agreement among a set of replicate measurements without assumption of knowledge of the true value. For EDS operations, precision is stated in terms of standard deviation, percent relative standard deviation (%RSD), relative percent difference (RPD), range, or relative range.

When stated as standard deviation, precision is calculated as follows:

$$S = \sqrt{\frac{\sum\left(x_i - \overline{x}\right)^2}{(n-1)}}$$

where

Σ	=	summation of the numbers
S	=	standard deviation for 1.0Z challenges
x_i	=	the ith measurement of the variable x
$\overline{x}$	=	mean
n	=	number of measurements.

and

$$\overline{x} = \frac{\sum x_i}{n}$$

When precision is calculated from three or more replicates, it is more commonly stated as %RSD and is calculated as follows:

$$\%\text{RSD} = \frac{\text{S}}{\overline{\text{x}}} \times 100$$

where

S	=	standard deviation
$\overline{x}$	=	mean of measurements.

When only duplicate measurements are available to calculate precision, the %RSD is calculated by the following equation:

$$\%RSD = \frac{100}{\sqrt{2}} \times \left[\frac{2(x_1 - x_2)}{(x_1 + x_2)} \right]$$

where x_1 and x_2 are the two measurements.

Another way to calculate precision when only two duplicate measurements are available is RPD, which is calculated as follows:

$$RPD = \left[\frac{2(x_1 - x_2)}{(x_1 + x_2)} \right] \times 100$$

13.2 Accuracy

Accuracy is the degree of agreement of a measurement with an accepted or true value. For chemical analyses, it is most commonly represented as percent recovery (%R).

For measurements where matrix spikes are used to measure accuracy, the %R is calculated as follows:

$$\%R = \left[\frac{x_s - x_u}{k}\right] \times 100$$

where

x_s = measured value for the spiked sample

x_u = measured value for the unspiked sample

k = known value of the spike in the spiked sample.

When a laboratory control sample is used to measure accuracy, the %R is calculated as follows:

$$\%R = \left[\frac{x_m}{x_{SRM}}\right] \times 100$$

where

x_m = measured value

x_{SRM} = true value of standard reference material in laboratory control sample.

The bias may be calculated from the %R as follows:

$$\%bias = \%R - 100 = \left[\frac{x_m}{x_{SRM}}\right] \times 100 - 100$$

13.3 Method Detection Limit (MDL)

The MDL is the minimum concentration of an analyte that can be measured and reported with 99 percent confidence that the analyzed concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. The MDL is calculated as follows:

$$MDL = t_{(n-1,1-\alpha=0.99)} \times S$$

where

$t_{(n-1,1-\alpha=0.99)}$	=	student's t value for a one-sided, 99-percent confidence level and a standard deviation estimate with n-1 degrees of freedom.
S	=	standard deviation of the replicate analysis.

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APPENDIX H-1
SUMMARY OF CRITICAL DATA

Table H-1-1. Summary of Critical Data to Be Collected for EDS Operations at DPG

Measurement Data to be Collected	Measuring Device	Collection Frequency	Frequency and Type of Quality Control Samples/Measurements
NRT Air Monitoring			
1. Determine presence of CWM in EDS workspaces	MINICAMS®	NRT monitoring is performed with a minimum frequency of once every 10 minutes.	Each MINICAMS is challenged with a field matrix spike sample once a day.
2. Determine CWM breakthrough for the AFS carbon filter systems	MINICAMS	NRT monitoring is performed with a minimum frequency of once every 10 minutes.	Each MINICAMS is challenged with a field matrix spike sample once a day.
3. Determine presence of CWM in the AFS carbon filter system exhaust	MINICAMS	NRT monitoring of the filter exhaust is performed with a minimum frequency of once every 10 minutes at both the midbed and stack (exhaust) locations.	Each MINICAMS is challenged with a field matrix spike sample once a day.
4. Determine presence of CWM in PDS	MINICAMS	NRT monitoring is performed with a minimum frequency of once every 10 minutes.	Each MINICAMS is challenged with a field matrix spike sample once a day.
Confirmation Air Monitoring			
5. Confirm presence of chemical agent in the EDS workspaces	DAAMS/GC	In the event of a NRT monitoring alarm, DAAMS tube samples being collected for area monitoring are analyzed to confirm the MINICAMS alarm.	DAAMS tubes used for chemical agent confirmation sampling are within the manufacturer's recommended shelf life and the GC used for analysis is challenged with a field matrix spike sample once a day.
6. Confirm breakthrough of chemical agent in the carbon filter systems	DAAMS/GC	In the event of a NRT monitoring alarm, DAAMS tube samples are collected and analyzed to confirm the MINICAMS alarm.	DAAMS tubes used for chemical agent confirmation sampling are within the manufacturer's recommended shelf life and the GC used for analysis is challenged with a field matrix spike sample once a day.

Table H-1-1. Summary of Critical Data to Be Collected for EDS Operations at DPG (Continued)

Measurement Data to be Collected	Measuring Device	Collection Frequency	Frequency and Type of Quality Control Samples/Measurements
7. Confirm presence of chemical agent in the carbon filter system exhaust	DAAMS/GC	In the event of a NRT monitoring alarm, DAAMS tube samples are collected and analyzed to confirm the MINICAMS alarm.	The DAAMS tubes used for chemical agent and confirmation sampling are within the manufacturer's recommended shelf life and the GC used for analysis is challenged with a field matrix spike sample once a day.
<u>Area Air Monitoring</u>			
8. Area Monitoring to detect presence of chemical agent in EDS workspaces	DAAMS/GC	DAAMS tube samples are continuously collected. At 8-hour intervals the tubes are exchanged for fresh sampling tubes. The used sampling tubes are sent to the laboratory for analysis.	The DAAMS tubes used for chemical agent confirmation sampling are within the manufacturer's recommended shelf life and the GC used for analysis is challenged with a field matrix spike sample once a day.
<u>Detection Monitoring</u>			
9. Determine if decontaminated PPE or equipment meets Army decontamination requirements for maximum residual offgas before transport to laundry or shipment to an approved TSDF	MINICAMS or DAAMS/GC	Upon completion of PPE decontamination procedures, vapor monitoring is conducted for the bag or container holding the decontaminated PPE.	Each MINICAMS is challenged with a field matrix spike sample once a day.
10. Determine the presence of chemical agent vapors in EE workspaces after decontamination for closure	MINICAMS or DAAMS/GC	After completion of closure decontamination procedures, the EE MINICAMS monitors are used to monitor the EE workspaces.	Each MINICAMS is challenged with a field matrix spike sample once a day.

Table H-1-1. Summary of Critical Data to Be Collected for EDS Operations at DPG (Continued)

Measurement Data to be Collected	Measuring Device	Collection Frequency	Frequency and Type of Quality Control Samples/Measurements
11. Determine the presence of chemical agent in carbon filter systems after decontamination for closure	MINICAMS or DAAMS/GC	After completion of closure decontamination procedures, the EE MINICAMS monitors are used to monitor the filter system housing.	Each MINICAMS is challenged with a field matrix spike sample once a day.
12. Determine the presence of chemical agent vapors for clean closure of the EE workspaces	DAAMS/GC	When EE is ready for clean closure, the exhaust system is turned off and the EE sampled continuously for 8 hours using DAAMS tubes.	The DAAMS tubes used for chemical agent confirmation sampling are within the manufacturer's recommended shelf life and the GC used for analysis is challenged with a field matrix spike sample once a day.
13. Determine the presence of chemical agent vapors for clean closure of the filtration systems	DAAMS/GC	When EE is ready for clean closure, the exhaust system is turned off and the filter housings are sampled continuously for 8 hours using DAAMS tubes.	The DAAMS tubes used for chemical agent confirmation sampling are within the manufacturer's recommended shelf life and the GC used for analysis is challenged with a field matrix spike sample once a day.
Waste Management			
14. Determine time and date that each waste container is sent to temporary storage	Watch and calendar	For each drum of waste removed from the EE, the time and date of removal are noted and recorded, along with the waste drums identification number.	N/A
15. Determine weight of a waste container removed from the EE	Scale	The weight for each waste container is measured and recorded along with the container identification number and date and time the container is removed from the EE.	N/A

Table H-1-1. Summary of Critical Data to Be Collected for EDS Operations at DPG (Continued)

Measurement Data to be Collected	Measuring Device	Collection Frequency	Frequency and Type of Quality Control Samples/Measurements
16. Establish time and date that a waste drum is placed into or removed from service	Watch and calendar	Each time an empty or partially-filled waste drum is placed in a waste receptacle station in the EE to be filled with hazardous waste, the time and date are recorded along with the container identification number. Each time a filled or partially-filled hazardous waste drum is removed from a waste receptacle station in the EE to be sent to temporary storage, the time and date are recorded along with the container identification number.	N/A

Notes:

[a] In the event of a potentially exposed worker, there is a MINICAMS located in the PDS to perform low-level NRT monitoring.

AFS = air filtration system
CWM = chemical warfare materiel
DAAMS = Depot Area Air Monitoring System
EDS = Explosive Destruction System
EE = Environmental Enclosure
GC = gas chromatograph
N/A = not applicable
NRT = near real-time
PDS = Personnel Decontamination Station
PPE = personal protective equipment
TSDF = treatment, storage, and disposal facility

Table H-1-2. Summary Estimate of Analytical Samples

Sample Source	Analyte	Analytical Method	Turn Around Time	Number of Sampling Events	Samples per Event	Total Number of Samples	Duplicate Samples[a]	Replicate Samples[a]	Trip Blank	Grand Total
Solids Waste Samples										
	Chemical agent	Vapor Screening	Normal	1[b,c]	1	1[b,c]	0	0	0	1[b,c]
Sub-total				1		1	0	0	0	1
Neutralization and Rinsewater Samples										
	Chemical agent	Extraction and GC/MSD	Normal	3[c]	1	3	0	0	0	3
Sub-total				3		3	0	0	0	3
Used Filter Samples										
	Chemical agent	MINICAMS®	Normal	1	1	1	0	0	0	1
Sub-total				1		1	0	0	0	1
Used Decontaminated Disposable PPE										
	Chemical agent	MINICAMS	Normal	1	1	1	0	0	0	1
Sub-total				1		1	0	0	0	1
Aqueous Personnel Decontamination Station										
	Chemical agent	GC/MSD	Normal	1	1	1	0	0	0	1
		EE Closure Decontamination Rinsate	Normal	1	1	1	0	0	0	1
Sub-total				2		2	0	0	0	2
Grand Total				8		8	0	0	0	8

Table H-1-2. Summary Estimate of Analytical Samples (Continued)

Notes:

[a] Duplicate and replicate samples may be used to make matrix spike samples.
[b] Assumes one sample per processing event
[c] Assumes one sample for waste type/container generated

EE	=	Environmental Enclosure
GC/MSD	=	gas chromatograph/mass selective detector
PPE	=	personal protective equipment

APPENDIX H-2

CALIBRATION AND CHALLENGE CALCULATIONS

APPENDIX H-2

CALIBRATION AND CHALLENGE CALCULATIONS

List of abbreviations used in these calculations:

AEL	=	airborne exposure limit
L	=	liter
µg/mg	=	microgram per milligram
µL	=	microliter
mg/m^3	=	milligram per cubic meter
min	=	minute
mL	=	milliliter
mL/min	=	milliliter per minute
ng	=	nanogram
ng/µg	=	nanogram per microgram
ng/µL	=	nanogram per microliter

Air monitors must be able to detect analytes at the AEL for each analyte. Therefore, calibrations and challenges to the air monitors are conducted with an amount of standard solution (or gas) that will produce a 1.0 Z response from the monitor. ECBC will also perform a daily distal end (end of heat-traced sample line) low-level challenge of 0.25 Z (±50 percent lower level).

Calculations for Liquid Standards

For each chemical agent, an analyte solution is used for calibration and challenge.

Given: (using HD for example)

AEL	=	0.003 mg/m^3
Cycle time	=	6 min
Flow rate	=	150 mL/min
Concentration of standard solution	=	1.1 ng/µL

The mass of analyte required is calculated as follows:

Mass of analyte = AEL $\times$ cycle time $\times$ flow rate $\times$ conversion factors

Using HD example:

$$\text{Mass of analyte} = 0.003\ mg/m^3 \times 6\ min \times 150\ mL/min \times (1m^3/1{,}000\ L \times 1L/1{,}000\ mL \times 1{,}000\ \mu g/mg \times 1{,}000\ ng/\mu g$$

$$= 2.7\ ng$$

This calculation determines the mass of analyte that would be collected in the sorbent tube during one sampling cycle under the given conditions of cycle time and flow rate if the air contained 1.0 AEL of the analyte. Calculations for other concentrations may be performed by multiplying the mass of analyte needed to make a 1.0 AEL standard solution by a factor equal to the portion of the AEL that is desired. For example, to calculate the concentration for a standard solution at 0.2 AEL, multiply the mass of analyte needed for a 1.0 AEL solution by 0.2.

The volume of standard solution that must be injected into the monitor to produce a 1.0 AEL response is calculated as follows:

Volume of standard = mass of analyte/concentration of analyte in the standard

Using HD example:

Volume of standard = 2.7 ng/1.1 ng/µL
= 2.45 µL

The standard solutions for chemical agents are prepared by ECBC. The concentration of agent in the standard solution may vary from batch to batch; therefore, this calculation must be made for each new lot of analyte using the concentration value for that lot.

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